

**Draft U.S. Positions**

**CODEX COMMITTEE ON GENERAL  
PRINCIPLES**

**Eighteenth Session**  
**Paris, France, 7 - 11 April 2003**  
**To be held at the Centre International de Conférences BERCY,**  
**139 rue de Bercy, 75012 Paris**  
**from Monday 7 April 2003 at 10.00 to Friday 11 April 2003**

## 2. Matters Referred by the Codex Alimentarius Commission and other Codex Committees

[CX/GP 03/2](#)

### DRAFT U.S. Position

*When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.*

This statement, developed in relationship to a discussion on the Codex “Working Principles of Risk Analysis,” was adopted by the 24<sup>th</sup> Session of the Commission.

In the “Matters Referred” document, it is stated that: “The Executive Committee noted, however, that there was no guidance on how to interpret or apply this principle, especially in the establishment of maximum residue limits for veterinary drug residues and pesticides, and also for microbiological contamination. It agreed that such guidance would be useful when considering either proposals for new work or when considering texts for adoption (ALINORM 03/3A, paragraph 66-70).”

The United States questions the need for the development of guidance in this area. It would appear that this is an issue for the more specialized committees, rather than CCGP. With respect to microbiological contaminants, guidance already exists within Codex for the establishment of microbiological criteria; such guidance would form the basis for developing microbiological criteria by CCFH. With respect to undertaking new work on veterinary drugs, pesticide residues and food additives, the current policy of CCFAC, CCRVDF and CCPR is to not recommend a review of a chemical unless sufficient scientific evidence is available to undertake a JECFA or JMPR review. After the specialized, main risk assessment committees have addressed this question, CCGP may have a role in assuring that there is consistency across committees.

Therefore, The United States does not support the development of guidance in this area.

### **3. Risk Analysis**

#### **a) Draft Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius**

[ALINORM 03/33 Appendix II](#)

CL 2002/38-GP

Government Comments at Step 6 [CX/GP 03/3](#)

Comments from Brazil CX/GP 03/3-Add.1

#### **DRAFT U.S. Position**

The United States generally supports the advancement of the Draft Working Principles for Risk Analysis for Application in the Framework of Codex Alimentarius for adoption at the 26<sup>th</sup> Session of the Codex Alimentarius Commission.

The U.S., however, has a few corrections to the text that we would like to see made before it is advanced:

- 1) In the last sentence of paragraph 20, insert the word “scientific” between the words “qualitative” and “information” to make clear that the reference to scientific data in the first sentence applies to both quantitative and qualitative information.
- 2) The second sentence of paragraph 35 refers to “the need for alternative options”. The U.S. believes that this sentence intended to refer to the need to evaluate alternative options. There may be situations in which, based on the scientific analysis, there is only a single, viable risk management option. The “need for alternative options” should not necessarily be a general principle of risk analysis.
- 3) The U.S. questions the need for footnote 3 regarding a definition for “legitimate confidential information.” This term has been used for years by CCFAC and JECFA with no confusion over what was covered and what must be made available.

### 3. Risk Analysis

#### b) Proposed Draft Working Principles for Risk Analysis for Food Safety

CL 2002/39-GP

Government Comments at Step 3 [CX/GP 03/4](#)

#### DRAFT U.S. POSITION

In response to CL 2002/39-GP, the United States submitted detailed comments on the *Proposed Draft Working Principles for Risk Analysis for Food Safety*. Those comments are contained in CX/GP-03/4, and will be reiterated by the United States during discussion of this agenda item.

The United States would like to call the Committee's particular attention to our general comment submitted in response to CL 2002/39-GP. The United States noted that: "As acknowledged in Annex 1, few changes were made to the sections on general aspects, risk assessment, and risk assessment, with the most significant changes in the section on risk management. Therefore, the document looks very much like the set of principles intended for application within the framework of Codex."

The United States notes the instructions given to the Committee by the Commission in paragraph 75 of ALINORM 01/41:

*"It also agreed that the Committee should develop guidance to governments subsequently or in parallel, as appropriate in view of its programme of work."*

Therefore, the U.S. questions whether the proposed form of guidance (i.e., principles only) is the most useful. The question is one of whether principles alone are sufficient guidance for governments.

This issue should be addressed before CCGP initiates a "line-by-line review of Annex 2 to CL 2002/39-GP, since once a line-by-line discussion is initiated, fundamental changes to the document in either content and/or format become much more difficult to accomplish.

In regards to the appropriate form of guidance, the United States notes that key Codex committees, including the Codex Committee on Food Hygiene (CCFH), the Codex Committee on Food Additives and Contaminants (CCFAC) and the Codex Committee on Pesticide Residues (CCPR) all have texts under development related to the application of risk analysis and its component parts. In particular, the text under development by CCFH, *Principles and Guidelines for Microbiological Risk Management*, includes elements relating to the application of microbiological risk management both by Codex and by countries. Much of this work may have applicability to the development of a Codex risk analysis text for use by countries, or may, in some situations, be used in lieu of a CCGP developed text on the subject.

The United States also notes that an alternative approach to the current "Principles" document might be to use the reports of the FAO/WHO Expert Consultations on Risk Assessment, Risk Management and Risk Communication to develop a "Guideline" on "how to apply risk analysis at the country level". Such a text may incorporate many of the same elements but might have a much different structure, with more practical advice for countries to follow, instead of paragraphs stated as principles. Elements that could be further expanded in guidance to countries could include: priority setting for risk assessment and risk management, interaction between risk

assessors and risk managers, selection of risk management options, allocation of resources, and use of peer review.

In any case, the United States believes that CCGP should carefully consider the best approach to developing appropriate risk analysis guidance for use by countries before proceeding further with the development of the current *Proposed Draft Working Principles for Risk Analysis for Food Safety*.

The United States believes that it would be worthwhile for CCGP to explore, in conjunction with CCFH, CCFAC, CCRVDF and CCPR, how best to proceed with the development of appropriate risk analysis guidance for use by countries before proceeding further with the current Principles text. This work might be initiated through discussions between the Chairs of these Committees, working in conjunction with the Codex Secretariat. It would also be helpful for the Codex Secretariat, as a result of these discussions, to prepare a Discussion Paper on the subject for consideration by CCGP at its next Session.

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON GENERAL PRINCIPLES**

**Eighteenth Session**

**Paris, France**

**April 7-11, 2003**

**COMMENTS RELATING TO THE PROPOSED DRAFT WORKING PRINCIPLES  
FOR RISK ANALYSIS FOR FOOD SAFETY**

**Comments provided by the United States**

The United States would suggest to the Codex Committee on General Principles an alternative approach to the development of guidance to countries on the subject of the application of risk analysis for food safety.

The United States calls the Committee's attention to our general comment submitted in response to CL 2002/39-GP. The United States noted that: "As acknowledged in Annex 1, few changes were made to the sections on general aspects, risk assessment, and risk assessment, with the most significant changes in the section on risk management. Therefore, the document looks very much like the set of principles intended for application within the framework of Codex."

The United States suggests that the Committee should seriously consider whether the proposed form of guidance (i.e., principles only) is the most useful. The question is one of whether principles alone are sufficient guidance for governments.

This issue should be addressed before CCGP initiates a "line-by-line review of Annex 2 to CL 2002/39-GP, since once a line-by-line discussion is initiated, fundamental changes to the document in either content and/or format become much more difficult to accomplish.

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The United States also notes that an alternative approach to the current “Principles” document might be to use the reports of the FAO/WHO Expert Consultations on Risk Assessment, Risk Management and Risk Communication to develop a “Guideline” on “how to apply risk analysis at the country level”. Such a text may incorporate many of the same elements but might have a much different structure, with more practical advice for countries to follow, instead of paragraphs stated as principles. Elements that could be further expanded in guidance to countries could include: priority setting for risk assessment and risk management, interaction between risk assessors and risk managers, selection of risk management options, allocation of resources, and use of peer review.

The United States believes that CCGP should carefully consider the best approach to developing appropriate risk analysis guidance for use by countries before proceeding further with the development of the current *Proposed Draft Working Principles for Risk Analysis for Food Safety*.

The United States suggests that it would be worthwhile for CCGP to explore, in conjunction with CCFH, CCFAC, CCRVDF and CCPR, how best to proceed with the development of appropriate risk analysis guidance for use by countries before proceeding further with the current Principles text. This work might be initiated through discussions between the Chairs of these Committees, working in conjunction with the Codex Secretariat. It would also be helpful for the Codex Secretariat, as a result of these discussions, to prepare a Discussion Paper on the subject for consideration by CCGP at its next Session.

#### 4. Proposed Draft Revised Code of Ethics for International Trade in Foods

[CX/GP 03/5](#)

Government comments at Step 3 CX/GP 03/5- Add.1

##### **DRAFT U.S. Position**

The United States appreciates the work that has been accomplished in the development of the Revised Code of Ethics for International Trade in Foods, as drafted.

The United States has several specific comments to suggest on the text. Our general comment on the draft text, however, is that care should be taken to assure that the scope of the document focuses on the Codex mandate, that is, consumer health and fair trade. In a document dealing primarily with ethics in fair trade, it is easy to stray into areas that do not fall within the Codex mandate but which are, nevertheless, of interest to members and may indirectly be related to fair trade practices. Issues outside of the mandate of Codex, such as those relating to the lack of access to food for populations suffering from hunger and malnutrition, are important issues that fall outside the scope of the Codex mandate. It might, however, be possible for CCGP to achieve consensus on a document solely related to the mandate of Codex. Extending the discussion to include other issues will make progress on this document very difficult.

Given the status of Codex texts under the trade agreements, the U.S. questions how Codex envisions the implementation of this code. From the document as drafted it is not clear that this is an advisory text. There needs to be a more complete discussion of the status of this code.

The U.S. believes that until these fundamental problems are addressed, no resources should be expended on developing the text of the Code.

##### **Specific Comments**

###### Article 1 – Objective

This Code is advisory in nature and not necessarily intended to be adopted into national legislation. Therefore, Article 1.2 should be revised to read:

*"The code is advisory to member governments, those engaged in international trade in food, and citizens to aid in judging whether trade practices are acceptable."*

###### Article 2 – Scope

The U.S. would rewrite 2.2 to read:

*"The code serves as advice for ethical conduct of food trade to member governments."*

###### Article 5 - Specific Requirements

In 5.1, the U.S. supports the wording "taking into account", as this is consistent with member country obligations under the WTO trade agreements.



## Article 6 – Implementation

6.1(d) we believe is redundant with 6.2 and, therefore, should be deleted.

In the paragraph following 6.1(d), we agree that unsafe food (i.e., "food [that] represents a hazard to health") should not be exported, but we feel this point is captured in the phrase "that food complies with the regulations of the importing country and is exported in accordance with the requirements of the importing country". Further, because generally it is commercial firms, rather than countries, that export foods, we would also suggest alternative wording to "a country may export food". Thus, we suggest the following revisions to this sentence:

*"Food that does not comply with national regulations of the exporting country may still be exported if that food complies with the regulations of the importing country and is exported in accordance with the requirements of the importing country."*

6.4 We believe the initial phrase in 6.4 "Except when the food represents a hazard to health" should be deleted. Foods that contain residues marginally exceeding an MRL in one country may be considered legally to "represent a hazard to health" within that particular country. In another country, they may be considered as "safe food" under the law. In any case, the reason for the rejection of the shipment should be provided to either the exporting or another country to which the rejected shipment is shipped. Thus, taking both these comments into account, 6.4 would read:

*"Food that has been exported and subsequently rejected may be allowed to be re-exported to the exporting country along with the reasons for shipment rejection; or*

*allowed to be re-exported to another country only if the reasons for the rejection are disclosed to the potential importer before re-export."*

## Article 7 - Responsibilities for Implementation

In the first 7.2 (obviously a numbering error), the U.S. supports the wording "taking into account", with subsequent deletion of "[apply]" and the second set of brackets.

## **5. Membership in the Codex Alimentarius Commission of Regional Economic Integration Organizations**

[CX/GP 03/6](#)

Information provided by the EC CX/GP 03/6-Add.1

### **DRAFT U.S. Position**

#### **Issue**

The Codex Committee on General Principles (CCGP) at its April 2003 meeting will be invited to consider draft amendments to the Codex Rules of Procedure to enable the membership in Codex of Regional Economic Integration Organizations (REIOs), in particular that of the European Community (EC). The CCGP further will be asked to transmit the draft amendments to the Codex Alimentarius Commission (CAC) for formal adoption at the next meeting of the CAC in June/July 2003.

#### **U.S. Position**

The U.S. is prepared to support the proposed amendments to the Codex Rules of Procedure to permit the full membership of REIOs only if procedural and substantive concerns regarding EC membership are satisfactorily addressed. These include the lack of clarity in the delineation of competence on food safety issues between the EC and its Member States (MS); the potential harm the lack of clarity on competence could have on Codex procedures; and, in cases of mixed competency and consensus decision making, uncertainty as to whether the proposed amendments to the Codex procedures will undermine the principle of "no additionality." The U.S. position will be reviewed following the April 2003 meeting of the CCGP and prior to the June 2003 CAC.

#### **Draft Comments**

- The U.S. has reviewed carefully the proposed amendments to the Codex Rules of Procedure that would enable Regional Economic Integration Organizations to become full members of Codex. The European Community (EC) has proposed these changes in order to become a member to be represented by the European Commission.
- The U.S. notes that the EC, represented by the European Commission, currently is an active participant in Codex as an Observer.
- The U.S. believes that EC participation in a treaty body or international organization should not give its Member States (MS) relative advantages over other states.
- At the same time, the U.S. recognizes there are circumstances where the EC represents the interests of its Member States and thus can play an important role in certain international organizations in which Member States participate.

- In the case of Codex, however, EC-Member State competence for food safety issues is mixed, generating concerns that EC membership in Codex could impair the management of Codex meetings, the organization's operations and procedures, and its decision-making.
- Before the U.S. would be able to consider supporting EC membership in Codex, the EC should provide a more detailed and precise statement regarding the delineation of competence.
- The U.S. welcomes the additional information provided by the European Community regarding its Declaration of Competence (CX/GP 03/6-Add.1). While providing useful detail, it also raises new questions regarding the distribution of competence between the EC and its Member States and the implications for Codex.
- To minimize confusion and uncertainty for Committee Chairs and participating Members of Codex, particularly in instances where competency is shared between the EC and the Member States, the U.S. believes the proposed amendments to the Codex Rules of Procedure must be clarified.
- The proposed procedural amendments must be carefully considered to avoid providing the EC or the Member States additional rights or benefits at the expense of other Members.
- The goal of accepting REIO and EC membership should be to improve Codex. EC membership, should it occur, must be structured so there is no harm to Codex operations, procedures and decision-making, and that no relative disadvantage accrues to any current non-EU member nation of Codex.

## 6. Consideration of Traceability/Product Tracing

CX/GP 03/7

### DRAFT U.S. Position

The United States believes that there is a role for product tracing in relation to food safety and that Codex should give priority to considering product tracing as a risk management “tool”. There must be a clear distinction between food safety and non-food-safety product tracing. These must be maintained as two separate areas of discussion. The U.S. notes that different disciplines apply to food safety and non-food safety issues under the SPS and TBT Agreements, respectively. The U.S. believes that product tracing systems for non-food-safety reasons (i.e., where product identity must be maintained through appropriate channels as in “organic” or “Halal”) should be voluntary and market-driven. The U.S. does not support mandatory product tracing programs for reasons other than food safety.

The United States supports the statement on product tracing of the Coordinating Committee for North America and the South West Pacific (CCNASWP), found in paragraph 52 of ALINORM 03/32. However, the U.S. has serious concerns about the apparent misinterpretation of the CCNASWP statement presented in CX/GP 03/7. Specifically in paragraph 9, CX/GP 03/7 indicates that product tracing for the purposes of food safety and for matters other than food safety cannot be separated. The paper states that “once there is the ability to trace a product, that product can be traced for whatever purpose.” CCNASWP was careful to state that product tracing must be considered on a case-by-case basis. In paragraph (g), the CCNASWP statement specifically states:

*“The need for and scope of application and specifications regarding each element of product tracing should be considered on a Case-by-case basis according to the objective(s) of the food control system within which product tracing is implemented.”*

Therefore, before considering the requirements of, or even to some extent the principles involved in, a product tracing system, the objective of such a system must be first determined.

Accordingly, the U.S. questions the statement in paragraph 9 of CX/GP 03/7 that “product tracing has the benefit of being applicable to the management of previously unknown or unidentified risks. This implies that a product tracing system is adequate to address any hazard and its associated risk that might be identified in the future. Without knowing the objective, a product tracing system cannot be devised. Accordingly, the U.S. also does not support the statement in paragraph 13 that product tracing is neutral to the objective for which product tracing may be implemented.

Regarding paragraph 17 that deals with the development of a definition: The United States does not believe that Codex should use or define the term “traceability”. The U.S. puts forward the following definition for “product tracing” related to food safety.

**Product Tracing:** The ability to identify by means of paper or electronic records a food product and its producer, from where and when it came, and to where and when it was sent.

Regarding the development of a guideline, or working principles, on the application of “product tracing/traceability” as a risk management tool (paragraph 18), the U.S. notes that work in this area has been undertaken by CCFICS. Parallel, and potentially contradictory, work should not be undertaken by CCGP.

While the rationale for focusing work on product tracing in CCFH (paragraph 19) has some merit (especially to focus product tracing work on food safety), the U.S. would prefer to permit work on product tracing within CCFICS to progress further before making this decision. The U.S. reaches this conclusion after considering the extensive current workload of CCFH, and the more appropriate expertise of CCFICS (food program operations) to deal with an operational entity (product tracing) as opposed to the scientific expertise of CCFH.

The U.S. does not support the development of a general text dealing with the question of verification of specific labeling and claims. Codex should complete work on the food safety aspects of product tracing before becoming engaged in the non-safety areas.

## **Statement from the Codex Coordinating Committee for North America and the South West Pacific**

- a) That the term “product tracing” is the appropriate terminology to employ for the concept of the tracing of food products and/or their ingredients. The Codex Ad-Hoc Intergovernmental Task Force on Foods Derived from Biotechnology reached consensus on the use of this term and, subsequently, the term is gaining acceptance within Codex.
- b) ) In considering product tracing, Codex should give priority to considering its use as a tool with respect to risk management.
- c) That product tracings can be considered to include the following possible elements:
  - The ability to identify a food (product identification);
  - how the food product was changed, if appropriate; and, where the food product came from and to where it was sent - one step forward and one step backward (product information); and,
  - Linkages between product identification and product information.
- d) That the use of product tracing within a food control system be consistent with the provisions of the WTO SPS and TBT Agreements. In this regard, provisions relating to product tracing should, as appropriate to the application:
  - Be science based.
  - Be consistent with fair trade practices criteria.
  - Be subject to equivalence determinations.
  - Be no more trade restrictive than necessary.
- e) That product tracing is not a stand-alone activity, i.e., it is a tool that may be applied within a broader food control system.
- f) That product tracing requirements must have clear justification with respect to food safety and/or ensuring fair practices in food trade.
- g) That the need for and scope of application and specifications regarding each element of product tracing should be considered on a case-by-case basis according to the objective(s) of the food control system within which product tracing is implemented. For example, whether product tracing should be applied within a specific portion of the food chain or whether such tracing may be required across two or more links in the food chain would be dependent on the objectives to be achieved by the food control system.
- h) That decisions on whether a mandatory product tracing system should be implemented should be based on whether such an approach is necessary to achieve the objectives of the food control system.
- i) That certain other considerations may apply to product tracing, including, for example, that product tracing be:
  - Outcomes based;
  - Cost effective;
  - Practical; and,
  - Enforceable.

## 7. Guidelines for Cooperation with International Intergovernmental Organizations

[CX/GP 03/8](#)

### DRAFT U.S. Position

CX/GP 03/8, *Guidelines for Cooperation with Intergovernmental Organizations*, presents three situations under which cooperation may exist:

1. The elaboration of a joint standard or related text with a cooperating organization,
2. The elaboration of a Codex standard or related text by a cooperating organization on behalf of the Codex Alimentarius Commission, and
3. Substantial cooperation at the initial drafting stages of a Codex standard or related text.

Looking at the three suggested situations individually:

#### **The elaboration of a joint standard or related text with a cooperating organization:**

The United States notes that the Joint FAO/WHO Evaluation of Codex recommended the joint elaboration of standards. Therefore, it may be premature for the Codex Committee on General Principles to develop this form of cooperation further until the Commission has considered the Evaluation report and its recommendations and decided how recommendations, if accepted, would be implemented. However, the U.S. has two major concerns with the Proposed Draft Guidelines contained in CX/GP 03/8. In paragraph 7(c), the Commission will decide whether the procedures of Codex or the procedures of the cooperating organization will be followed. The U.S. believes that for a text to be accepted as a Codex standard or related text, Codex procedures must be followed. Codex procedures provide the degree of transparency and inclusiveness required for texts to be accepted by consensus. In paragraph 8, a text would become a Codex standard if adopted by the Commission and by the cooperating organization. The U.S. believes that for a text to become a Codex standard it need be accepted by only the Codex Commission.

#### **The elaboration of a Codex standard or related text by a cooperating organization on behalf of the Codex Alimentarius Commission**

The United States has serious reservations about this option for cooperating with other intergovernmental organizations. Firstly, any organization developing a standard for Codex must have the same inclusiveness of membership and observer organizations as found in Codex. The U.S. questions whether there are many organizations that would meet these requirements. Secondly, with the recent institution of *ad hoc* Intergovernmental Task Forces, Codex should have sufficient flexibility to develop its own texts.

#### **Substantial cooperation at the initial drafting stages of a Codex standard or related text**

The United States recognizes that it is important for Codex to take advantage of expertise found in other organizations and believes that this form of cooperation is worthy of further

consideration. However, any text being so developed must enter the Codex procedures at Step 3 for full consideration by member governments. This is especially critical if the Joint FAO/WHO Evaluation report recommendation to limit the Codex Step Procedure to 5 steps is accepted and implemented.